

## SELF-MANAGEMENT STRATEGIES ACROSS CHRONIC DISEASES

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National Institute of Nursing Research  
National Heart, Lung, and Blood Institute  
National Institute on Aging  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
National Institute of Child Health and Human Development  
National Institute of Diabetes and Digestive and Kidney Diseases  
National Institute of Mental Health  
National Institute of Neurological Disorders and Stroke

THIS PA USES THE "MODULAR GRANT" AND "JUST-IN-TIME" CONCEPTS. IT INCLUDES DETAILED MODIFICATIONS TO STANDARD APPLICATION INSTRUCTIONS THAT MUST BE USED WHEN PREPARING APPLICATIONS IN RESPONSE TO THIS PA.

### PURPOSE

The purpose of this Program Announcement (PA) is to solicit applications to expand research on established self-management interventions to multiple chronic diseases across the life-course. Interventions aimed at chronic disease self-management are numerous and many are well described in the literature. They are often presented as specific to a particular chronic disease. This PA encourages applicants to investigate the applicability of effective self-management interventions to a broader spectrum of chronic diseases. Chronic disease, for this announcement, is defined as illnesses that are prolonged, are rarely cured completely, and require self-management behaviors by affected individuals and/or their caretakers.

### HEALTHY PEOPLE 2010

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS led national activity for setting priority areas. This PA, Self-Management Strategies Across Chronic Diseases, is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople/>.

## ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as principal investigators.

## MECHANISM OF SUPPORT

This PA will use the National Institutes of Health (NIH) Research Project Grant (R01) award mechanism. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for an application submitted in response to this PA may not exceed 5 years.

Specific application instructions have been modified to reflect "MODULAR GRANT" and "JUST-IN-TIME" streamlining efforts being examined by the NIH. Complete and detailed instructions and information on Modular Grant applications can be found at <http://grants.nih.gov/grants/funding/modular/modular.htm>

## RESEARCH OBJECTIVES

Self-management behavior, to some degree, has been an expectation for individuals with a chronic disease for much of the past century. The concept of self-management and its practice, however, is changing. A more proactive self-management role is being promoted rather than a health care provider giving instructions and hoping the patient will adhere to them. Individuals with a chronic disease are being involved in a more active role. Effective self-management today includes a broad range of health, lifestyle, and self-assessment and treatment behaviors by the individual, often with assistance and support of others. The promotion and maintenance of a healthful and satisfying life, in the presence of chronic disease, requires individuals to assume both leadership and partnership roles with health care providers.

The Centers for Disease Control and Prevention (CDC) reports that nearly three quarters of adults age 65 years and older have one or more chronic illnesses, and nearly half report two or more. With an aging population, chronic diseases will increase proportionately. Children and

young people who have a chronic disease can expect to live longer and, therefore, will have a need to manage their health condition(s) over a longer life span than in the past. With an increasing life span, older individuals will require more health services longer for chronic health conditions. Medical care costs for people with chronic diseases today are more than \$400 billion annually, accounting for more than 60% of total medical care expenditures. Furthermore, the CDC reports that 7 of every 10 deaths in the U.S. are due to chronic diseases.

The cost of health care for individuals with chronic illnesses does not typically consider the personal, occupational, and financial costs related to self-management or disabilities. Nor does it account for the social and psychological burdens placed on the individual, the family, and society as a whole by the 90 million Americans with one or more chronic diseases. The personal and social costs can be affected by improving and supporting healthy lifestyle and self management behaviors of those affected by chronic disease.

Researchers have developed many effective interventions for chronic disease self-management. Many of these interventions, however, were developed in one chronic disease population and not adequately tested in other chronic disease populations. Studies have shown, for example, that interventions involving social support, provider-client interactional style, improved self-efficacy, problem solving or coping skills, and certain follow-up activities have a positive impact on self-management and health outcomes in specific chronic diseases. This affects both affected individuals and significant others. Caregiving knowledge and expertise relevant to diabetes management are often critical for family members and others assisting dependent children and elders. Even without a caregiving component, families and significant others are affected by a member's chronic condition and its lifestyle and care requirements.

There is growing interest in the public health arena and across disciplines in interventions that can be applied across chronic diseases. This initiative to extend current research to test the effectiveness of self-management interventions across chronic diseases is a logical next step. Standard interventions requiring minimal adaptation to a particular disease have the potential to be more cost effective and less complicated to translate into practice than those requiring extensive adaptation to each health condition. Effective self-management interventions for identified chronic diseases and populations are the expected outcomes of such research. The study of interventions with a high potential for effectiveness and efficacy across several chronic diseases may increase the generalizability of findings and maximize the effectiveness of research and health care dollars.

Scope

This Program Announcement solicits proposals to further test established interventions for self-management in new populations and across chronic diseases not previously tested, or adequately tested, for the intervention. There is a particular interest in extending previously validated interventions to different chronic disease populations. All age and ethnic groups are of interest. Examples of approaches include (a) comparing intervention strategies across two or more groups, each with a different chronic disease or (b) comparing intervention strategies in a single population with two or more chronic diseases. Methodology should include common outcome measures for the intervention across chronic diseases as well as disease-specific outcome measures.

The following research topics are provided as examples that would extend the current knowledge base. They are not listed in any priority order and are not intended to be inclusive or restrictive.

- o Investigate intervention strategies that promote chronic illness self-management across chronic diseases in which they have not been adequately or previously tested;
- o Test intervention strategies that promote self-monitoring, health behaviors, problem solving, and decision making across chronic diseases;
- o Develop standard approaches to promotion and support of self-management across chronic disease conditions;
- o Determine the influence of established approaches to self-management across chronic diseases (examples: improved self-efficacy, cognitive strategies, social support, coping skills, provider-client partnership);
- o Examine the influence of quality of life, burden of care, culture, ethnicity, age, family, or socioeconomic status across chronic diseases on self-management;
- o Determine whether age-, gender-, and ethnically-related motivational factors are associated with improved self-management of chronic diseases in children.
- o Investigate how the multiple co-morbidities and disabilities associated in the most advanced years affect the types of self-management strategies chosen as well as the effectiveness of different approaches;
- o Test evidence-based clinical guidelines across settings for different age, ethnic, or socioeconomic groups across chronic diseases; and
- o Determine provider roles/approaches and care coordination systems that are most effective in providing seamless, continuous care that promotes effective self-management across chronic diseases.

NHLBI: Self-management strategies are applicable to a number of blood diseases. For example, self monitoring of coagulation status is now possible with new technologies leading to more precise adjustment of medications. Self-monitoring also allows home therapy of patients with deep vein thrombosis utilizing low molecular weight heparin. Patients are increasingly encouraged to adjust and administer treatments such as iron chelation therapy for those with secondary iron overload secondary to chronic transfusion, and pain medication for those with sickle cell disease and recurrent crises. The patient with hemophilia can now administer clotting factor at home substantially reducing hospitalization and time lost from school and work. New communication technologies that link health care providers with patients also facilitate increasing patient empowerment to monitor and manage their own chronic blood disease. Innovative proposals to use self-management strategies to reduce healthcare disparities are especially encouraged.

NIA: NIA is interested in understanding biological, behavioral, and social factors that affect the aging process and the health and quality of life of older persons. We are especially interested in the interaction of disease and care factors with proposed studies explicitly examining the role of aging and life-course factors in disease onset, progression and/or management. While all age-related chronic conditions are of interest to NIA, we encourage research that investigates multiple morbidities common in old age. Self-management issues associated with Alzheimer's disease and related disorders are of particular interest.

NIAMS: The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) is interested in the design, development and testing of new and improved self-management programs for rheumatic and related diseases such as arthritis, lupus, scleroderma and fibromyalgia, disorders of the musculoskeletal system, and diseases of muscle, bone, and skin. Within these areas, the Institute encourages the development of self-management programs that target women, children and disproportionately affected patient populations

NIMH: The NIMH encourages applications that explicitly and centrally explore the role of mental disorders/symptoms/related disability. We are particularly interested in studies on modifiable risk and protective processes and the development and initial testing of new interventions. The interventions may be pharmacologic, behavioral, or psychosocial.

NINDS: The National Institute of Neurological Disorders and Stroke (NINDS) is interested in the development and evaluation of interventions for initiation and maintenance of self-management activities applicable to patients with chronic neurological disorders (e.g., epilepsy) and stroke. Self-management interventions for patients with neurological disorders and stroke require

special adaptation to reflect psychiatric co-morbidities and cognitive deficits in these patients. Interventions for stroke patients need to address multiple self-management activities, including drug regimens and lifestyle changes.

#### INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification are provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and in the NIH Guide for Grants and Contracts, Vol. 23, No. 11, March 18, 1994 and is available on the web at the following URL address: <http://grants.nih.gov/grants/guide/notice-files/not94-100.html>

#### INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: <http://grants.nih.gov/grants/guide/notice-files/not98-024.html>

Investigators also may obtain copies of these policies from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

#### NOTE FOR APPLICATIONS FOCUSED ON AGING RESEARCH

Applications received in response to this program announcement are expected to focus on scientific issues related to aging and to aging-related aspects of disease. In describing the plan to recruit human subjects, investigators may cite a focus on aging or on aging-related aspects of disease as the justification for why children will be excluded. In this regard, applicants may use Justification 1, the research topic to be studied is irrelevant to children, from the policy announcement.

#### URLS IN NIH GRANT APPLICATIONS OR APPENDICES

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

#### APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 4/98) and will be accepted at the standard application deadlines as indicated in the application kit. Application kits are available at most institutional offices of sponsored research and may be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, email: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov).

Applicants planning to submit an investigator-initiated new (type 1), competing continuation (type 2), competing supplement, or any amended/revised version of the preceding grant application types requesting \$500,000 or more in direct costs for any year are advised that he or she must contact the Institute or Center (IC) program staff before submitting the application, i.e., as plans for the study are being developed. Furthermore, the application must obtain agreement from the IC staff that the IC will accept the application for consideration for award. Finally, the applicant must identify, in a cover letter sent with the application, the staff member and Institute or Center who agreed to accept assignment of the application.

This policy requires an applicant to obtain agreement for acceptance of both any such application and any such subsequent amendment. Refer to the NIH Guide for Grants and Contracts, March 20, 1998 at <http://grants.nih.gov/grants/guide/notice-files/not98-030.html>

The modular grant concept establishes specific modules in which direct costs may be requested as well as a maximum level for requested budgets. Only limited budgetary information is required under this approach. The just-in-time concept allows applicants to submit certain information only when there is a possibility for an award. It is anticipated that these changes will reduce the administrative burden for the applicants, reviewers and Institute staff. The research grant application form PHS 398 (rev. 4/98) is to be used in applying for these grants, with the modifications noted below.

## SPECIFIC INSTRUCTIONS FOR MODULAR GRANT APPLICATIONS

### BUDGET INSTRUCTIONS

Modular Grant applications will request direct costs in \$25,000 modules, up to a total direct cost request of \$250,000 per year. (Applications that request more than \$250,000 direct costs in any year must follow the traditional PHS 398 application instructions.) The total direct costs must be requested in accordance with the program guidelines and the modifications made to the standard PHS 398 application instructions described below:

#### PHS 398

- o FACE PAGE: Items 7a and 7b should be completed, indicating Direct Costs (in \$25,000 increments up to a maximum of \$250,000) and Total Costs [Modular Total Direct plus Facilities and Administrative (F&A) costs] for the initial budget period. Items 8a and 8b should be completed indicating the Direct and Total Costs for the entire proposed period of support.

- o DETAILED BUDGET FOR THE INITIAL BUDGET PERIOD - Do not complete Form Page 4 of the PHS 398. It is not required and will not be accepted with the application.

- o BUDGET FOR THE ENTIRE PROPOSED PERIOD OF SUPPORT - Do not complete the categorical budget table on Form Page 5 of the PHS 398. It is not required and will not be accepted with the application.

- o NARRATIVE BUDGET JUSTIFICATION - Prepare a Modular Grant Budget Narrative page. (See <http://grants.nih.gov/grants/funding/modular/modular.htm> for sample pages.) At the top of the page, enter the total direct costs requested for each year. This is not a Form page.



o Under Personnel, List key project personnel, including their names, percent of effort, and roles on the project. No individual salary information should be provided. However, the applicant should use the NIH appropriation language salary cap and the NIH policy for graduate student compensation in developing the budget request.

For Consortium/Contractual costs, provide an estimate of total costs (direct plus facilities and administrative) for each year, each rounded to the nearest \$1,000. List the individuals/organizations with whom consortium or contractual arrangements have been made, the percent effort of key personnel, and the role on the project. Indicate whether the collaborating institution is foreign or domestic. The total cost for a consortium/contractual arrangement is included in the overall requested modular direct cost amount. Include the Letter of Intent to establish a consortium.

Provide an additional narrative budget justification for any variation in the number of modules requested.

o BIOGRAPHICAL SKETCH - The Biographical Sketch provides information used by reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. A biographical sketch is required for all key personnel, following the instructions below. No more than three pages may be used for each person. A sample biographical sketch may be viewed at:

<http://grants.nih.gov/grants/funding/modular/modular.htm>

- Complete the educational block at the top of the form page;
- List position(s) and any honors;
- Provide information, including overall goals and responsibilities, on research projects ongoing or completed during the last three years.
- List selected peer-reviewed publications, with full citations;

o CHECKLIST - This page should be completed and submitted with the application. If the F&A rate agreement has been established, indicate the type of agreement and the date. All appropriate exclusions must be applied in the calculation of the F&A costs for the initial budget period and all future budget years.

o The applicant should provide the name and phone number of the individual to contact concerning fiscal and administrative issues if additional information is necessary following the initial review.

The title and number of the program announcement must be typed on line 2 of the face page of the application form and the YES box must be marked.

Submit a signed, typewritten original of the application, including the Checklist, and five signed photocopies in one package to:

CENTER FOR SCIENTIFIC REVIEW  
NATIONAL INSTITUTES OF HEALTH  
6701 ROCKLEDGE DRIVE, ROOM 1040, MSC 7710  
BETHESDA, MD 20892-7710  
BETHESDA, MD 20817 (for express/courier service)

#### REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established PHS referral guidelines. Applications will be evaluated for scientific and technical merit by an appropriate scientific review group convened in accordance with the standard NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed, assigned a priority score, and receive a second level review by the appropriate National Advisory Council.

#### Review Criteria

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that the application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

(1) Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

(2) Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

(3) Innovation: Does the project employ novel concepts, approaches or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

(4) Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

(5) Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

In addition to the above criteria, in accordance with NIH policy, all applications will also be reviewed with respect to the following:

- o The adequacy of plans to include both genders, minorities and their subgroups, and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

- o The reasonableness of the proposed budget and duration in relation to the proposed research

- o The adequacy of the proposed protection for humans, animals or the environment, to the extent they may be adversely affected by the project proposed in the application.

Additional scientific/technical merit criteria specific to the objectives of the PA and the mechanism used must be included if they are to be used in the review.

AWARD CRITERIA

Applications will compete for available funds with all other recommended applications. The following will be considered in making funding decisions: Quality of the proposed project as determined by peer review, availability of funds, and program priority.

## INQUIRIES

Inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding GENERAL ISSUES to:

Dr. Nell Armstrong  
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National Institute of Nursing Research  
Building 45, Room Number 3AN12, MSC 6300  
Bethesda, MD 20892-6300  
Telephone: (301) 594-5973  
FAX: (301) 480-8260  
Email: [nell\\_Armstrong@nih.gov](mailto:nell_Armstrong@nih.gov)

Direct inquiries regarding specific PROGRAMMATIC ISSUES to the staff of the appropriate Institute/Center:

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Direct inquiries regarding FISCAL MATTERS to:

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#### AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.361 (NINR); 93.839 (NHLBI); 93.866 (NIA); 93.846 (NIAMS); 93.865 (NICHD); 93.849 (NIDDK); 93.242 (NIMH); and 93.853 (NINDS). Awards are made under authorization of sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and administered under NIH grants policies and Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, and portion of a



facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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